File Date: 10/5/2012

Case No: 12cv8004

ATTACHMENT # 5

EXHIBIT

TAB (DESCRIPTION)

Covered Services: Covered services under the Medicare and other third-party payment programs are the services and supplies for which Medicare or other third parties will reimburse. Covered services under the Medicaid program consist of a combination of mandatory and optional services within each State. Covered services under the Medicare and Medicaid programs are defined and limited by federal statute. Covered services under private health benefit programs are defined and limited by contract.

Current Procedural Terminology (CPT-4): A system of procedure codes and descriptions published annually by the American Medical Association. This procedure coding system is accepted by virtually all commercial insurance carriers and is required by Medicare and Medicaid.

Cross-Over Patient: A patient who has both Medicare and Medicaid coverage.

Customary Charge: The provider's standard charge for a given service.

D

Deductible: A stipulated amount which the insured is required to pay toward the cost of medical treatment before the benefits of the insurance policy or program takes effect. Deductibles are usually per year of coverage and are required before any benefits are payable.

Denial: The refusal of an insurer to cover an item or service under a health care plan or program.

Dependents: The spouse and children of the insured as defined in the insurance contract.

Diagnosis: The physician's determination of a patient's condition, sign, or symptom, using the ICD-9-CM coding system.

Diagnosis Related Group (DRG): A system of classifying medical cases for payment on the basis of diagnoses. Used under Medicare's prospective payment system (PPS) for inpatient hospital services.

Durable Medical Equipment (DME): DME is any equipment that usually can withstand repeated use, is useable at home, and is not beneficial to a person without an illness or injury. Splinting, orthopedic bracing, and wheelchairs are good examples of DME.

Date of Service (DOS): The date a service was provided to an individual under a particular health plan.

E

Electronic Claim: A claim form that is processed and delivered from one computer to another via magnetic media (e.g. magnetic tape, diskette) or via telecommunications (telephone link).

Encounter Data: Claims that are not paid fee-for-service because they are the responsibility of the provider under the capitation agreement.

Enrollee: An individual who is enrolled for coverage under a health plan contract and who is eligible on his/her own behalf (not by virtue of being an eligible dependent) to receive the health services provided under the contract.

Evaluation & Management Service: A non-technical service provided by physicians for the purpose of diagnosing and treating diseases and counseling and evaluating patients.

Exclusion: Specific services or conditions which the health insurance policy or program will not cover, or which are covered at a limited rate.

Experimental Procedures: Medical procedures for which basic safety or effectiveness is still in doubt and that depend on still-to-be-completed research studies or laboratory experiments involving animals.
Explanation of Benefits (EOB): A form included with a check from the insurer which explains the benefits that were paid and/or charges that were rejected.

F

Fee for Service: Refers to paying medical providers for individual services rendered. UCR, CPR and Fee Schedules are examples of fee for service systems.

Fee Schedule: A list of predetermined payments for medical services. Medicare Part B reimburses physicians based on a fee schedule.

Fiscal Intermediary (FI): An intermediary is an organization that has an agreement with the US Department of Health and Human Services (DHHS) to process claims and perform other functions under Medicare's Hospital Insurance program. Hospitals and skilled nursing facilities may select the intermediaries through which bills would be submitted for services to Medicare beneficiaries.

G

Gatekeeper: A primary care physician responsible for managing all aspects of a patient's care, including referrals to specialists and hospital stays. HMO members select a primary care physician, who serves as a gatekeeper to other services proved by the HMO.

Geographic Practice Cost Indices (GPCI): Additional calculation used to adjust payment based on geographic location. A complete list of geographic factors is available on the Federal Register.

Global Payment: Prospectively defined limits on spending for some portion of the healthcare industry, such as hospital operating budgets or both hospital and physician services.

Global Service: A package of clinically related services treated as a unit for purposes of billing, coding, or payment.

Global Surgery Policy: The payment policy in the Medicare Fee Schedule stating that the global surgical fee includes not only the procedure itself but also all related services and visits that occur within a designated time period (generally 90 days). Separate payment is permitted for the initial evaluation, services for unrelated problems, and return trips to the operating room for complications.

H

Health Care Financing Administration (HCFA): The U.S. Government agency with responsibility for the administration of the Medicare and Medicaid programs. On June 14, 2001, the agency name changed to the Centers for Medicare and Medicaid Services (CMS).

HCFA 1500: A universal insurance claim form mandated for Medicare billing and generally accepted by all insurance carriers for outpatient-based health care providers. Physicians and medical suppliers use the HCFA 1500 claim form.

HCFA Common Procedure Coding System (HCPCS): A three-level coding system, consisting of: CPT, National or Level 2, and Local or Level 3 codes. CPT and National Level 2 codes are recognized and used by the majority of health care insurers.

Health Maintenance Organization (HMO): Prepaid health plans that provide a range of services in return for fixed monthly premiums or other payment method.

I

ICD-9-CM: International Classification of Diseases, 9th Revision, Clinical Modifications. This is a standardized system of describing diagnoses and procedures. Diagnoses are maintained by the World Health Organization; HCFA shares responsibility for procedure codes intended for use by hospitals.

Incidental Procedure: A procedure that is an integral part of another procedure and therefore not allowable as a separately reimbursable benefit.

Independent Practice Association (IPA): A type of HMO that contracts with individual doctors to provide services to its members. IPA physicians see HMO patients in their own offices. They are free to contract with more than one HMO at a time, as well as see patients outside of the HMO.

Initial (Claim) Determination: The first adjudication made by a Carrier or Fiscal Intermediary (FI) (i.e. the Medicare affiliated contractor) following a request for Medicare (or insurance) payment or the first determination made by a PRO either in a prepayment or post-payment context.

Inpatient: An individual who has been admitted to a hospital as a registered bed patient and is receiving services under the direction of a physician for at least 24 hours.

Insured: The person who represents the family unit in relation to the insurance program (usually the employee whose employment provides health insurance coverage).

Insurer: A commercial insurance company or other entity, which pays for health care benefits.

Intermediary: Under Medicare, contracts with HCFA to administer benefits under Part A.

Investigational Procedures: Medical procedures thought to have medical benefit in some circumstances, but the precise clinical indications and protocols for treatment still have not been sufficiently standardized and, therefore, further clinical trials involving human beings are needed.

L

Length of Stay (LOS): The length or number of days an individual stays in an inpatient setting.

M

Managed Health Care Plan: One or more products which integrate financing and management with the delivery of health care services to an enrolled population; employs or contracts with an organized provider network which delivers services and which (as a network or individual provider) either shares financial risk or has some incentive to deliver quality, cost-effective services; uses an information system capable of monitoring and evaluating patterns of members' use of medical services and the cost of those services.

Mandated Benefits: Those benefits which health plans are required by state or federal law to provide to policyholders and eligible dependents.

Medicaid: A State/Federal government sponsored Medical Assistance Program to enable eligible recipients to obtain essential medical care and services.

Medical Necessity: Medical information justifying that a service rendered was reasonable and appropriate for the diagnosis or treatment of a medical condition.

Medicare: A federal health insurance program for people 65 or over and for disabled persons with chronic renal disorders.

Medicare+Choice: Under the Balanced Budget Act of 1997 (BBA97), Congress created a new Medicare Part C, known as Medicare+Choice, which allows CMS to contract with a number of managed care organizations including, but not limited to, health maintenance organizations, preferred provider organizations, provider service organizations, and medical savings accounts. Beneficiaries have the choice during an open enrollment season each year to enroll in a Medicare+Choice plan or to remain in traditional Medicare.

Medicare Contractor: An organization that enters into a legal agreement with the US Dept of Health and Human Services (DHHS) to handle specified administrative, payment and review functions. Contractors include Fiscal Intermediaries (Part A contractors), Carriers (Part B contractors), Health Maintenance Organizations (HMOs), Competitive Medical Plans (CMPs), and Utilization and Quality Control Peer Review Organizations (PROs). These organizations are charged with the responsibility of assuring payments are made only for services covered under Medicare Part A or Part B. They determine whether a particular service is covered under Medicare in the course of adjudicating a Medicare claim or conducting utilization and quality review.

Medigap Insurance: Healthcare policies which provide benefits for services and costs not covered by Medicare, such as deductibles, co-insurance or items not covered under the Medicare program.

Member: A participant in a health plan (subscriber/enrollee or eligible dependent) who makes up the plan's enrollment.

Modifier: A two-position code used supplementary with CPT or HCPCS codes to indicate that the service has been changed in some way.

N

National Medicare Coverage Decisions: A reimbursement decision on an individual healthcare technology that is made by CMS and issued as national policy. The policy is published in CMS regulations, published in the Federal Register as a final notice, contained in a CMS ruling, or issued as a program instruction. These decisions are binding on all Medicare contractors.

Non-Covered Service: The service: 1) does not meet the requirements of a Medicare benefit or insurance plan category, or 2) is statutorily excluded from Medicare coverage on grounds other than 1862(a)(1) or is not reasonable and necessary under 1862(a)(1).

Nonparticipating Physician (Medicare): A physician who does not sign a Medicare participation agreement, and therefore is not obligated to accept assignment on all claims.

O

Outlier: A case that is substantially different from the rest of the population. With regard to hospital payment, these are classified as cases with extremely long lengths of stay (day outliers) or extraordinary high costs (cost outliers) compared with others in the same DRG. Hospitals receive prospective payment system (PPS) payments for these cases. In DRG parlance, an atypical hospital case that falls at the extremes of a distribution.

Outpatient Hospital Service: Services furnished to patients who are registered on the hospital records as an outpatient for diagnosis or treatment of an illness or injury.

P

Part A (Medicare): The Medicare Hospital Insurance Program, which covers hospital and related institutional care.

Part B (Medicare): The Medicare Supplementary Medical Insurance Program (SMI), which covers the costs of physician services, outpatient lab, x-ray, DME and certain other health services.

Participating Provider: A hospital, pharmacy, physician, or ancillary services provider who has contracted with a health plan to provide medical services for a determined fee or payment.

Payer: An entity, which is liable to pay for the medical costs of an injury, disease or disability of a person.

Point of Service Plan (POS): The newest type of managed care organization, which differs from others in one critical aspect. Insureds who decide to go outside the plan for health care services receive reduced benefits.

Precertification: A method for pre-approving all elective hospital admissions, surgeries, and other provider services as required by insurance carriers. Approval is essential before payment for services is received.

Preferred Provider Organization (PPO): An arrangement whereby an insurer or managing entity contracts with a group of health care providers who furnish services at lower than usual fees in return for prompt payment and a certain volume of patients.

Primary Care Provider (PCP): A healthcare professional who acts as a member's personal healthcare manager. The PCP evaluates a patient's medical condition and either treats the condition or coordinates required healthcare services.

Principal Diagnosis: The diagnosis which, after study, is judged to be the principal reason for hospitalization or other medical care.

Professional Component (-PC aka -26): The part of a relative value or fee that represents the cost of a physician's interpretation of a diagnostic test or treatment planning for a therapeutic procedure.

Professional Review Organization (PRO): A physician-sponsored organization charged with reviewing the services provided to patients. The purpose of the review is to determine if the services rendered are medically necessary; provided in accordance with professional criteria, norms and standards; and provided in the appropriate setting.

PPS (Prospective Payment System): Under Medicare, payments to hospitals for inpatient services are prospectively determined amounts based on the DRG assigned at discharge.

Preauthorization: A process that allows physicians and other health care providers to determine, before treatment, if a patient and/or service is eligible for coverage of a proposed treatment or service.

Prospective Reimbursement: Any method of paying hospitals or other health care providers for a defined period of time according to amounts or rates of payment established in advance (i.e., capitation).

Primary Insurer: The insurance plan has first responsibility under Coordination of Benefits.

Prior Authorization: An assessment of health care services by the insurer in advance of provision of services by the provider. This may be required under the health care plan or program. It may also be performed routinely by the provider to ensure coverage and payment.

Provider: The person in relation to the insurance plan or program who provides health care services. Under Medicare, providers denote only hospitals; physicians and suppliers are excluded from the definition of the term.

R

Reasonable and Customary Charge: A charge for health care, which is consistent with the going rate in a geographic area for identical or similar services.

Reimbursement: The amount paid for a covered service.

Resource Based Relative Value Scale (RBRVS): A government mandated relative value system implemented January 1992 that is used for calculating national fee schedules for services provided to Medicare patients. Physicians are paid on Relative Value Units (RVUs) for procedures and services. The three components of each established value are: work RVU, practice expense RVU and malpractice expense RVU.

S

Secondary Insurer: The insurer that is second in responsibility under Coordination of Benefits.

Self-funding, Self-insurance: A health care program in which employers fund benefit plans from their own resources without purchasing insurance. Self-funded plans may be self-administered, or the employer may contract with an outside administrator for an Administrative-Services Only (ASO) arrangement.

Staff Model HMO: This health care model employs physicians to provide health care to its members.

Subscriber: The person responsible for payment of premiums or whose employment is the basis for eligibility for membership in an HMO or other health plan.

T

Technical Component (-TC): The provision of equipment, supplies, technical personnel, and costs associated with a procedure or treatment other than the professional services. The -TC modifier is generally associated with the provider who owns or is responsible for the equipment, supplies, etc.

Third-Party Administrator (TPA): An organization that processes health care claims without bearing any insurance risk.

TRICARE (formerly CHAMPUS): A federally funded health benefits program, administered by the Department of Defense, designed to provide health care benefits to eligible veterans and their dependents.

U

UB-92: A uniform billing form required for submitting and processing claims for institutional providers. It merges billing information with diagnostic codes, including almost all of the elements from the uniform hospital discharge data set. UB-92 is also called the HCFA-1450 form.

Unbundling: The process of coding, billing and requesting payment for services that are generally included in a global charge.

Usual, Customary, and Reasonable (UCR): A term indicating fees charged for medical services that are considered normal, common and in line with the prevailing fees in the provider's area.

Utilization Management: Activities that include preadmission, admission and concurrent review, second surgical opinion, discharge planning, individual case management and focused review.

Utilization Review: The process of reviewing services to determine if those services are or were medically necessary and appropriate.

V

Veterans Health Care Program: A program providing health care services for military veterans.

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J

EXHIBIT

J

400 and 600 micron core single use optical laser fibers

Instructions for Use

READ ALL INSTRUCTIONS THOROUGHLY BEFORE USE.

1. **Description**

The Optical Integrity Fiber is a fiber optic laser delivery system consisting of a 2 or 3 meter long silica fiber, clad in HCS, buffered with a fluorinated acrylate and with a shaped tip. As an integral part of a laser system, the Optical Integrity Laser fiber may be used for a wide variety of surgical procedures.

- The Optical Integrity Fibers are designed for use with laser systems having transmission between 532 and 1400 nm (i.e. ND:Yag, KTP or Diode laser systems) that have been cleared for medical use and accept standard SMA 905 connectors (with threaded or luer fittings).
- The Optical Integrity Fiber is a single use disposable product that is supplied sterile.
- This product is design to be used by physicians that are familiar with the physiological applications and have been trained in proper use and operation of surgical laser systems

2. **Indications**

The Optical Integrity Fibers are intended to be used for vaporization, cutting, ablation, and coagulation of soft tissue in conjunction with endoscopic equipment including laparoscopes, hysteroscopes, arthroscopes, bronchoscopes, cystoscopes, ureteroscopes, gastroscopes, colonoscopes, or for open surgery for contact or non-contact surgery with or without hand piece for use in coagulation, incision/excision, ablation, and vaporization of soft tissue.

The Optical Integrity Fibers are indicated for use in medicine and surgery in the following specialties: Urology, Plastic Surgery, Radiology, Dermatology, Pulmonology, Gastroenterology, Gynecology, ENT, Lithotripsy, General and Vascular Surgery, Arthroscopy, Podiatry, Orthopedics, and Neurosurgery.

3. **Potential Complications**

Complications could include local and/or systemic infection, thermal damage to surrounding structures, local hematoma, dissection and perforation, tissue adherence, distal tip detachment, and discomfort during and/or after energy application. In the unlikely event of a detached tip, it may be visually located through an appropriate scope and removed using forceps. Irrigate the area thoroughly to remove any traces of the tip.

4. **Precautions**

- Use of Optical Integrity laser fibers on laser systems not recommended, may result in harm to patient or user or damage to the laser. Optical Integrity laser fibers are recommended for HO:Yag, ND:Yag, KTP or Diode laser systems that have been cleared for medical use and accept SMA 905 connectors.
- Tissue stuck to the end of the fiber can cause burn back. This problem with laser fibers occurs because the tissue can carbonize and cause energy to be adsorbed back into the fiber creating thermal runaway wherein the fiber tip heats up very rapidly. Visible light other than the aiming beam, (sometimes seen as a flash of white light) is evidence that the fiber is burning back, and is an indication that tissue is stuck to the lasing tip. Because of this phenomenon, no laser fiber should be used if tissue is stuck to the end of the fiber. If this occurs, remove the fiber from the patient and wipe the tip with a soft tissue. If the debris cannot be removed, the fiber tip must be cleaved and the buffer stripped back for

a fresh surface. (See the Striping and Cleaving section of this instruction)

- When cleaning do not use side pressure as this may damage the tip.
- Increased laser exposure time will result in a deeper and wider zone of necrosis.
- Do not bend fiber at sharp angles.
- Care should be exercised with the glass tip to avoid severe impacts or side stresses that may fracture the tip.
- The time for treating a specific target area may be different when using the Optical Integrity laser fiber compared to using other shaped fibers. A different beam divergence and a laser spot size may alter treatment times.
- During each lasing interval, it is helpful to move the distal tip up and back 1 to 2mm to prevent the tip from sticking to tissue.
- Immediately discontinue use if breaks or fractures appear in laser fiber. These breaks or fractures may allow undirected emission of laser energy, rendering the distal tip useless and potentially causing harm to surrounding tissues.
- Always wear appropriate protective eyewear during the delivery of laser energy.
- Do not use the Optical Integrity laser fiber in the presence of flammable anesthetics or any combustible materials.

5. **Instructions for use**

1. Prior to activation of the laser, review the Laser Operator's Manual for instructions on the proper set-up and operation of the laser system.

! Caution: Do not exceed the maximum wattage or minimum fiber size ratings for fibers on the laser. See table in item 10 below

2. Remove the fiber from the sterile pouch using aseptic technique.

! Caution: **Do not use if the pouch has been opened or if there is visual damage to the pouch.**

3. Make sure the laser is "OFF" or on "STANDBY" mode before inserting the fiber into the laser aperture port. Attach the SMA 905 connector to the laser and finger tighten until a secure connection is achieved.
4. Handle the fiber with care as damage may occur if struck or bent sharply. If the fiber delivery system is damaged during use, it should not be repaired.
5. Activate the laser aiming beam and carefully inspect the full length of the fiber for breaks. These will appear as bright red spots along the length of the fiber. When the tip is held about 3mm from a light colored surface, the laser aiming beam should be visible.
6. Perform Calibration of the laser (Calibration of the fiber is not required) – See Laser Operator's Manual. Note: there are no known reciprocal interferences posed by the laser fiber.
7. If no breaks are visible, the fiber is ready for use.
8. Begin treatment: With the laser in "STANDBY" mode, hold the probe about 5cm from the distal tip. If using an endoscopic delivery system, insert the probe until the tip extends approximately 1cm from the distal end of the endoscope. Adjust the laser power to the level appropriate for the intended use.